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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,385

06/28/2004

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,385	Applicant(s) NAGAOKA ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-8, 10-13, 15-17 and 23-26 is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 9 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/28/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-17 and 23-26 made without traverse in the reply filed on 04/24/2008 has been acknowledged.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the reagent container which comprises a hole forming device (as recited in claims 3, 7 and 12), containers having a dispensing mechanism (claims 13, 17) and the liquid outlet port at the "side opposite to the rotation center side", must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Currently, the drawings show reflectors disposed on the side of the constant temperature bath, not of the reaction container.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not

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be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 1 and 23 recite the bent flow path portion which “at a particular stage prevents the flow of liquid from the reagent containers which are connected to the capturing sections, and at another stage, forms the liquid flow”. Claim 3 also recites the reagent container comprising a hole forming device. Claims 13 and 17 recite containers which have a dispensing mechanism. Examiner found no support for these limitations in the specification.

Claim Objections

4. Claims 9 and 14 are objected to under 37 CFR 1.75(c) as being in improper form because it depends on multiple dependent claims 7, 8 and 12, respectively. See MPEP § 608.01(n). Accordingly, claim 9 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1-8, 10-13, 15-17 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, the containers “which are organized for capturing”, is unclear. In line 8, the “rotation center side”, lacks antecedent basis. It is also unclear whether or not the “outer periphery side” is the same with the “side opposite to the rotation center side”. The same considerations apply to claims 2, 4-5, 10, 15-17 and 23-24.

Claim 2 recites a *flow path which “connects* the capturing section and reagent containers which are *connected* to the capturing section and forms a reagent flow from the reagent containers to the capturing section using centrifugal force, and without providing valves”. It is unclear whether or not any valves are excluded and whether or not the containers are connected to the capturing section via some elements other than the flow path.

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In claim 5, the “reagent containers including washing solution containers”, is unclear. The reagent container and washing solution container of line 5 lack antecedent basis.

Referring to claims 10 and 15-17, the “downstream side of the capturing section” lacks antecedent basis. It is also unclear what structural features configure the containers for being specifically the specimen container, the washing solution container, or the mixture container.

In claim 24, the reagent outlet “which is positioned at the rotation center side to the same extent as the reagent outlet of the washing solution”, is unclear. The “subsequent washing step” lacks antecedent basis.

In claim 25, the inside of the structure” communicating with containers, lacks antecedent basis.

Claim 26 recites light being irradiated in the reagent container, It is unclear whether or not any irradiation means are intended.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-2, 4-6, 8, 10-11, 13, 15-17 and 23-26 are rejected under 35 U.S.C. 102(b) as anticipated by Schembri (US 5,472,603).

Schembri discloses an analytical device comprising, as shown in Figure 2, rotatable structure 40 which includes capturing section 60, a plurality of containers 41, 42, 46, 64 [‘reagent, specimen, storage, mixing or washing solution containers’] having exit passage 62 [‘outlet’] and connected to the capturing section 60 via flow path 50. The flow path includes elbow siphon 53 [‘bent section which returns to the rotation center side’] . “After the rotor ... slows sufficiently, capillary forces "prime" the siphon by pulling fluid just around the elbow. When the rotor is restarted, the combination of centrifugal and capillary forces draws the remaining fluid out of the holding chamber into the receiving chamber” (Col.3, lines 40-50).

With respect to claims 4, 8, 13 and 17, Schembri teaches chambers having a means “for introducing fluid therein. Introduction of fluid could be accomplished by any number of means known to the Artisan” (Col.4, lines 55 plus).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri in view of Kellogg et al. (US 6706519).

Although Schembri does not teach the container cover, this feature is very common in the art. See, for example, Figure 2 of Kellogg et al. showing cover 301 over rotational structure 201. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed such cover in the modified apparatus of Schembri, in order to provide clean environment for the test processes.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797